JUN 2 8 2005

9. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

Assigned 510(k) Number: K050967

Date of Summary Preparation: June 15, 2005

Manufacturer:
Sweden Diagnostics (Germany) GmbH
Munzinger Strasse 7
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Company Contact Person:
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Device Name: Varelisa ReCombi CTD Screen

Common Name:
Antinuclear antibody
immunological test system

Classification

Product Name	Product Code	Class	CFR
Varelisa® ReCombi CTD Screen	LJM	II	866.5100

Substantial Equivalence to

Varelisa® ReCombi ANA Screen (510(k) number: K993108)

Intended Use Statement of the New Device

Intended use/Indication for use

The Varelisa ReCombi CTD Screen EIA kit is designed for the qualitative determination of ten antinuclear antibodies in human serum or plasma to aid in the diagnosis of systemic rheumatic diseases such as SLE (systemic lupus erythematosus), drug-induced lupus, scleroderma (progressive systemic sclerosis), MCTD (mixed connective tissue disease), SS (Sjögren's syndrome) and polymyositis/dermatomyositis. The Varelisa ReCombi CTD Screen detects antibodies against dsDNA, RNP (RNP70,A,C), Sm (B,B',D), SS-A/Ro(52 kDa,60 kDa), SS-B/La, Scl-70, CENP-B, Histone, Ribosomal P Protein and Jo-1 in a single microwell.

Special condition for use statement

The device is for prescription use only.

Special instrument requirements

A microplate reader capable of measuring OD at 450 nm and 620 nm is required.

General Description of the New Device

The new device is an enzyme-linked immunosorbent assay (ELISA) using microtiter plates as the solid phase. The plate wells are coated with antinuclear antigens, which allow anti-nuclear antibodies (sample) to react with the immobilized antigens. The conjugate is rabbit anti-human IgG horseradish peroxidase (HRP), which uses 3, 3'5, 5' tetramethylbenzidine dihydrochloride (TMB) as substrate. The kit contains calibrator and negative control. The kit also contains sample diluent, wash buffer concentrate and stop solution.

Test Principle of the New Device

Varelisa ReCombi CTD Screen is an indirect noncompetitive enzyme immunoassay for the qualitative determination of 10 antinuclear antibodies in serum or plasma. The wells of a microplate are coated with human recombinant and native purified nuclear antigens and dsDNA. Antibodies specific for the nuclear antigens present in a patient sample bind to these nuclear antigens.

In a second step the enzyme labeled second antibody (conjugate) binds to the antigen-antibody complex which leads to the formation of an enzyme labeled conjugate-antibody-antigen complex. The enzyme labeled antigen-antibody complex converts the added substrate to form a colored solution.

The rate of color formation from the chromogen is a function of the amount of conjugate complexed with the bound antibody and thus is proportional to the initial concentration of the respective antibodies in the patient sample.

Device Comparison

The new device is developed as successor of the predicate device. Both assays share the same assay principle and indications for use. They are indirect noncompetitive enzyme immunoassays for qualitative determination of IgG antibodies against antinuclear antigens in serum and plasma. Both assays recommend the same sample dilutions and use identical reagents (including the conjugate). In accordance to the relevant scientific literature both assays state in the Intended Use, that the measuring of antinuclear antibodies aids in the diagnosis of Connective Tissue Diseases such as SLE (systemic lupus erythematosus), scleroderma (progressive systemic sclerosis), MCTD (mixed connective tissue disease), SS (Sjögren's syndrome) and polymyositis/ dermatomyositis.

Differences do exist but do not affect the tenor of the "Intended Use" and do not raise new types of "Safety and Effectiveness" questions. The new device uses two additional antigens (Histone, Rib-P) and a synthetic peptide derived from the human SmD protein plus recombinant SmBB´ instead of Sm antigen purified from calf thymus (complex consisting of SmBB' and SmD). Minor differences pertain to increased volumina of the reagents and leaving out the prewashing step of the antigen strips. The Wash buffer does no longer contain NaN3 and the substrate TMB is of lower concentration because the substrate incubation step is increased to 30 min.

Laboratory equivalence

The comparability of predicate device and new device is supported by a data set including

- results obtained for clinically defined sera and for international reference sera.
- results obtained for samples from apparently healthy subjects (normal population).
- results obtained within a comparison study analyzing 100 disease controls and 183 CTD samples.

Analysis of Agreement between individual test results and clinical definitions of samples.

	Varelisa ReCombi CTD Screen		Predicate Device		Difference between assays (%)	
	Agreement (%)	95% Confidence Interval (CI)	Agreement (%)	95% CI	Varelisa ReC. CTD Screen - Predicate Device	95% CI
Positive (CTD samples)	87.4	81.7 - 91.9%	85.2	79.3 - 90.0%	2.2	-1.7 – 5.0%
Negative (Control samples)	79.0	69.7 - 86.5%	84.0	75.3 - 90.6%	- 5.0	-11.8 - -0.2%

In summary, all available data support that the new device is substantially equivalent to the predicate device and that the new device performs according to state-of-the-art expectations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 28 2005

Mr. Michael Linss
Manager, Compliance and Quality
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Munzinger Strasse 7
D-79111 Freiburg, Germany

Re: k050967
Trade/Device Name: Varelisa ReCombi CTD Screen
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: Class II
Product Code: LJM
Dated: April 15, 2005
Received: April 18, 2005

Dear Mr. Linss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K050967

Device Name: **Varelisa ReCombi CTD Screen**

Indications For Use:

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Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Maria Chan

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K050967